GOVERNMENT OF INDIA
SCIENCE AND TECHNOLOGY
LOK SABHA

STARRED QUESTION NO:527
ANSWERED ON:11.05.2007
REGULATORY AUTHORITY FOR BIOTECHNOLOGY SECTOR
Barman Shri Hiten

Will the Minister of SCIENCE AND TECHNOLOGY be pleased to state:

(a) whether the Government proposes to set up an independent regulatory authority to develop the biotechnology sector in the country;

(b) if so, the details thereof; and

(c) the time by which it is likely to be set up?

Answer

MINISTER OF THE STATE IN THE MINISTRY OF SCIENCE & TECHNOLOGY AND MINISTER OF EARTH SCIENCES (KAPIL SIBAL)

(a), (b) & (c): A Statement is laid on the Table of the House.

THE STATEMENT REFERRED TO IN THE REPLY OF THE LOK SABHA STARRED QUESTION NO. #527 BY SHRI HITEN BARMAN TO BE ANSWERED ON 11.05.2007 REGARDING "REGULATORY AUTHORITY FOR BIOTECHNOLOGY SECTOR".

Indian biotechnology industry is on the growth path. Its turnover has already crossed a billion dollar mark, with a growth rate of around 40%. Biotechnology will be a major growth sector in India, where the Indian competitive advantage is increasingly evident. An appropriate policy and regulatory framework can be beneficial to the biotech industry as well as to the Indian society that directly benefits from the biotechnology.

There is need to ensure a high level of safety and efficacy of biotechnological products. This implies that there is need to have rigorous quality control system and enforcement mechanisms in place. Currently, safety assessment and commercialization of biotech products is regulated by various Committees under the Environment (Protection) Act 1986 and the Rules 1989 viz Review Committee on Genetic Manipulation (RCGM) in the Department of Biotechnology (DBT), Genetic Engineering Approval Committee (GEAC) in the Ministry of Environment & Forests (MoEF). Also, the recombinant pharma products are regulated under EPA as well as Drugs and Cosmetics Act 1940 and Rules 1945,thus making regulatory approvals time consuming and requiring multiple clearances. The multiple regulatory systems in India have been a cause of concern for some time for the industry. On the other hand, public concerns about the clinical trials and environmental safety also needed serious attention.

Towards streamlining and simplifying the approval process, the MoEF and Ministry of Agriculture (MoA) constituted two expert Committees under Dr. Mashelkar (Ex Director General, Council of Scientific & Industrial Research) for recombinant pharma products and Prof. M. S. Swaminathan (Chairman, Swaminathan Research Foundation, Chennai) for agriculture biotechnology products.These Committees have recommended establishment of an independent National Biotechnology Regulatory Authority (NBRA). As a follow-up of the recommendations, MoA submitted a Cabinet Note for establishing NBRA. Subsequent deliberations on the note by the Committee of Secretaries (COS), the Prime Minister's office has directed DBT to function as the administrative department for setting up of NBRA. The DBT is in the process of establishing the NBRA. Consultations with various stakeholders and the relevant procedures are being followed for obtaining proper approvals. Therefore, the time to be taken for its establishment cannot be defined at this moment.